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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,522	04/05/2001	John R. DePhillipo	GNLK-03	2835
76953 7590 06/20/2008 BRANDY C HILL P.O. BOX 951121			EXAMINER	
			MYERS, CARLA J	
LAKE MARY	, FL 32795		ART UNIT	PAPER NUMBER
			1634	
			MAIL DATE	DELIVERY MODE
			06/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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1. The amendment filed on April 18, 2008 amending the claims so that the claims are now directed to subject matter previously restricted in the Office action of September 1, 2004 is non-responsive (MPEP § 821.03). In the Office action of September 1, 2004, a restriction was required between the previously claimed polymorphisms and combinations of polymorphisms. In the response to this requirement, Applicant cancelled the claims directed to particular polymorphisms and combinations of polymorphisms. However, the claims as amended in the response of April 18, 2008 are once again directed to methods for detecting distinct combinations of polymorphisms. Accordingly, the claims are subject to the following restriction requirement:

Election / Restrictions

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - Claims 105, and 110-112 (in part), drawn to methods of selecting a dose
 of an anti-oxidant by assaying for a polymorphism at position -262 of a
 catalase gene and polymorphism resulting in an ala to val substitution at
 amino acid 9 of MnSOD, classified in class 435, subclass 6.
 - Claims 105, and 110-112 (in part), drawn to methods of selecting a dose
 of an anti-oxidant by assaying for a polymorphism at position -262 of a
 catalase gene and polymorphism resulting in an isoleucine to thymine
 substitution amino acid 58 of MnSOD, classified in class 435, subclass 6.
 - Claims 105, and 110-112 (in part), drawn to methods of selecting a dose
 of an anti-oxidant by assaying for a polymorphism at position -262 of a

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catalase gene and polymorphism resulting in an valine to glutamic acid substitution at amino acid 7 of CZSOD, classified in class 435, subclass 6.

- 4. Claims 105, and 110-112 (in part), drawn to methods of selecting a dose of an anti-oxidant by assaying for a polymorphism at position -262 of a catalase gene and polymorphism resulting in a cysteine to phenylalanine substitution at amino acid 6 of CZSOD, classified in class 435, subclass 6.
- 3. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and IV are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different mode of operation, function and effect and are mutually exclusive because the inventions require the detection of distinct combinations of polymorphisms. The chemical structure of each polymorphism is distinct from each of the other polymorphisms. For example, the polymorphism resulting in an ala to val substitution at position 9 of the MnSOD protein is chemically and functionally distinct from the polymorphism resulting in a cys to phe substitution at position 6 of the CZSOD protein. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

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Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required, and because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. Each the polymorphisms must be searched by a separate query of the electronic databases. See MPEP 808.02(C). Therefore, a search for methods which use each polymorphism or each combination of polymorphisms is not co-extensive with methods which use each of the other polymorphisms or each of the other combinations of polymorphisms, and subsequently, the search and examination for every combination of polymorphisms poses a serious burden on the examiner.

- 4. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:
 - (a) the inventions have acquired a separate status in the art in view of their different classification;
 - (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
 - (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
 - (d) the prior art applicable to one invention would not likely be applicable to another invention;
 - (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Since the above-mentioned amendment appears to be a *bona fide* attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634